K123849

510(k) SUMMARY

JAN 10 2013

DenTek Oral Care Inc.'s New Comfort-Fit® Dental Guard

Submitted in accordance with 21 CFR 807.92

Submitter's Name, Address, Telephone/Fax Number, Contact Person and Date Prepared:

DenTek Oral Care, Inc.
307 Excellence Way
Maryville, TN 37801
Phone: (865) 983-1300
Facsimile: (865) 983-2444

Contact: Linda Giles
Date Prepared: December XX, 2012

Name of Device: New Comfort-Fit® Dental Guard

Common or Usual Name: Dental Guard

Classification Name: Mouthguard, Over-the-Counter

Classification Product Code: OBR

Classification: Unclassified

Predicate Devices:

DenTek Oral Care Inc.'s Improved Comfort-Fit NightGuard (K081669).

Sleepright® Dura-Comfort® Dental Guard, formerly known as Sleepright® Advance, from Splintek - Power Products, Inc. (K071404).

Purpose of the Special 510(k) notice:

The New Comfort-Fit® Dental Guard is a modification to DenTek Oral Care Inc.'s Improved Comfort-Fit NightGuard (K081669).

Intended Use:

DenTek's New Comfort-Fit® Dental Guard is indicated for use for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and reduce the noise associated with bruxing or grinding.

Technological Characteristics:

The New Comfort-Fit® Dental Guard is a posterior-only occlusion dental guard, consisting of two bite pads connected by a buccal retention strap. The New Comfort-Fit® consists entirely of ELVAX, a thermoplastic material. The bite pads move along the buccal strap in order to adjust to the individual user needs, with the strap always contained within the walls of the bite pads. There are 5 positions of adjustability for each bite pad. Bumpers on the lingual wall of the bite pads keep the pads from rubbing against the lower gum line. The upper vertical bite pad wall creates a greater surface area for the cheek to rest against, providing enhanced retention for the guard.

Substantial Equivalence:

DenTek's New Comfort-Fit® Dental Guard has the same intended use and similar indications, principles of operation, and technological characteristics as DenTek's Improved Comfort-Fit NightGuard and Splintek's Sleepright® Dura-Comfort® Dental Guard. The minor modifications made to the device do not raise any new questions of safety or effectiveness. Thus, the New Comfort-Fit® Dental Guard is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 10, 2013

Ms. Linda Giles
Regulatory Specialist
DenTek Oral Care, Incorporated
307 Excellence Way
MARYVILLE TN 37801

Re: K123849
Trade/Device Name: New Comfort-Fit® Dental Guard
Regulation Number: Unclassified
Regulation Name: Mouthguard, Over-The-Counter
Regulatory Class: Unclassified
Product Code: OBR
Dated: December 13, 2012
Received: December 14, 2012

Dear Ms. Giles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123849

Device Name: New Comfort-Fit® Dental Guard

Indications for Use:

The New Comfort-Fit® Dental Guard is indicated for use for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and reduce the noise associated with bruxing or grinding.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.02 07:01:22 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: k123849